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The Veeda Newsletter

ISSUE 03: MAR 2020

STAY SAFE & AT HOME

LET'S FIGHT THE PANDEMIC TOGETHER

Regulatory
FDA Issues Guidance for Conducting Clinical Trials

Financial
Indian pharma to get US$ 1.3 billion boon

Clinical Research
COVID-19 Guidance for the Research Community

Merger and Acquisition
February 2020 pharmaceutical M&A round-up

Indian Pharma
Chinese firms resume export of pharma inputs to India

Message from our Executive Director
Mr. Ajay Tandon shares his thoughts on the global pandemic

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The Veeda Newsletter

ISSUE 03: MAR 2020

USFDA allows labs to test for coronavirus prior to review

As Coronavirus Disease 2019 (COVID 19) spreads to over 50 countries including the United States, the US Food and Drugs Administration (USFDA) announced a new policy to facilitate quick development and use of rapid COVID19 diagnostic tests by specialised laboratories in that country on February 29.

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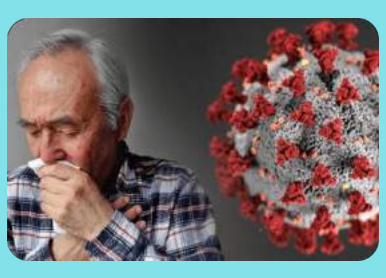
Regulatory status of equipment being used to help prevent coronavirus (COVID-19)

There are different regulations which apply to devices and equipment including hand gels and PPE (personal protective equipment)



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CDSCO Updates FAQs Drugs & Clinical Trial Rules 2019

Aimed at promoting clinical research in the country. Union Health Ministry notified the Drugs and Clinical Trials Rules, 2019 in the month of March 2019 As per the gazette notifications notifying the rules, they shall apply to all new drugs, investigational new drugs for human use, clinical trial, bioequivalence study, bioavailability study and Ethics Committee.

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FDA Issues Guidance for Conducting Clinical Trials

The U.S. Food and Drug Administration today issued a guidance for industry, investigators and institutional review boards conducting clinical trials during the coronavirus (COVID-19) pandemic.

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India Opens Regulatory Fast Track to COVID-19 Drugs, Vaccines and Diagnostics

The Central Drugs Standard Control Organization (CDSCO) of India has unveiled a series of actions designed to accelerate development of drugs, vaccines and diagnostics for use in the management of the COVID-19 pandemic.

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The Veeda Newsletter

ISSUE 03: MAR 2020

Pharma sales see rebound in February on back of respiratory drugs

Driven by respiratory drugs, the India Pharmaceutical Market (IPM) posted a double-digit growth of 12.1 percent for the month of February after underwhelming in December and January (8.8 percent and 7.7 percent), according to data by market research firm AIOCD-AWACS.

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The Impact Of Coronavirus Pandemic On The Indian Economy

As the scientific name for Coronavirus evolved in no time (currently called, the SARS-CoV-2) and so did its impact over the globe in terms of a pandemic & a health disaster, it has equally spelled disaster for the financial backbone of the world.

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Indian pharma to get US$1.3 billion boon

Against the backdrop of the COVID-19 pandemic in India, a US$1.3 billion fund will be established to bolster Indian pharma and promote domestic manufacturing to reduce import dependency.

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Coronavirus and the $2bn race to find a vaccine

Moderna is one of more than 20 companies and public sector organizations worldwide racing to develop a vaccine against Covid-19, which in little more than two months has exploded from a few people suffering from respiratory disease in the Chinese city of Wuhan to a near-pandemic with 95,000 cases and 3,300 deaths worldwide so far.

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Covid-19 to shave Rs 40k cr daily off economy; Q4 growth seen at 1.5-2.5%: Care Ratings

Assuming 300 working days in a year, the daily output comes to Rs 45-50,000 crore which can potentially be lost due to the shutdowns, says the report. Based on this, Q4 growth may not be negative but can go down to 1.5-2.5 per cent. The economy was slated to grow by Rs 1.74 lakh crore in Q4 or by 4.7 per cent.

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The Veeda Newsletter

ISSUE 03: MAR 2020

Discovering and designing drugs with artificial intelligence

In a landmark development, the first drug created using artificial intelligence (AI) has moved into its Phase I trial. Named DSP-1181, the compound was created in a joint venture between Exscientia and Sumitomo Dainippon Pharma for the treatment of obsessive-compulsive disorder (OCD).

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How to make the most of clinical trials

You finally have reached the time where you get to evaluate your product in a clinical trial. There are many important steps to keep in mind when advancing your project to this next level.

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Are Clinical Trials Doing Enough to Assess Patient Quality of Life?

Quality of life is only measured during the intervention stage of a clinical trial, according to a study published in JAMA Network Open, raising questions about how researchers gather patient-reported outcomes measures during clinical research.

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HHS Funds Clinical Trial for Potential COVID-19 Treatment

The Biomedical Advanced Research and Development Authority (BARDA), within the Assistant Secretary for Preparedness and Response (ASPR), part of HHS, will support the clinical trial to uncover whether Kevzara is an effective COVID-19 treatment.

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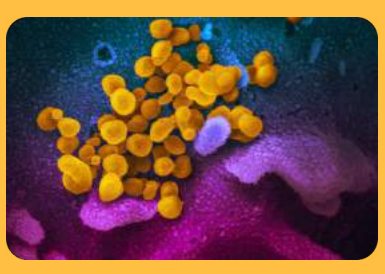
COVID-19 Guidance for the Research Community

Ongoing guidance about University of Minnesota research activities, updated when new information becomes available. See the Health Alert: Coronavirus (COVID-19) for the status of all University of Minnesota operations. With few exceptions, UMN researchers are working from home—see Working from Home Section below.



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The Veeda Newsletter

ISSUE 03: MAR 2020

Karo Pharma Completes the Acquisition of Product Portfolio from LEO Pharma

Karo Pharma Aktiebolag ("Karo Pharma") today announces that the acquisition of the intimate care and dermatology product portfolio from LEO Pharma for 90 MEUR, which was signed and announced by Karo Pharma on 23 December 2019 and approved by relevant competition authorities on 20 February 2020, has been completed.

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February 2020 pharmaceutical M&A round-up

For the second month in a row, there was a lack of sizeable acquisitions, though at least March has started with a bang, with US biotech Gilead Sciences (Nasdaq: GILD) agreeing to pay around $4.9 billion for immuno-oncology company Forty Seven, and Thermo Fisher Scientific (NYSE: TMO) acquiring Qiagen (NYSE: QGEN) for about $11.5 billion.

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Thermo Fisher to Acquire QIAGEN

Thermo Fisher Scientific Inc. has entered an agreement to acquire QIAGEN N.V., a global provider of molecular diagnostics and sample preparation technologies, in a transaction valued at approximately $11.5 billion

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Angelini Pharma Acquires ThermaCare® From GSK

Angelini Pharma announces today it has acquired the ThermaCare® global business rights, excluding North America, from GSK. The deal also includes the dedicated US manufacturing site for ThermaCare in Albany, Georgia.

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Shares Soar As Redx Pharma Receives Two Acquisition Offers, Agrees One

Redx Pharma PLC on Friday said it has received two separate acquisition offers, one from new shareholder Redmile Group LLC and the second from former suitor Yesod Bio-Sciences Ltd. Shares in Redx have multiplied to 13.48 pence each in morning trade Friday following the two bids. On Thursday, the stock ended at 4.50p.

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veeda clinical research

The Veeda Newsletter

ISSUE 03: MAR 2020

Niti Aayog soon to circulate draft Medical Devices Bill for stakeholders review

To address the regulatory vacuum and concerns of patient safety in medical devices, Niti Aayog is likely to circulate a draft of the Medical Devices Bill for stakeholders review to frame a separate medical devices Act much on the similar lines as drugs Act.

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DoP ensures drug security to handle coronavirus outbreak

Department of Pharmaceuticals has constituted a committee under the chairmanship of Dr. Eshwara Reddy, Joint Drugs Controller, Central Drugs Standard Control Organization (CDSCO) to address the issues of drug security in the country in the context of Novel Coronavirus outbreak in China.

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Central govt to launch iVEDA portal for tracking drugs meant for export soon

The central government will soon launch Integrated Validation of Exports of Drugs from India and its Authentication (iVEDA) portal for drug authentication and tracking and tracing of the drug supply.

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Chinese firms resume export of pharma inputs to India

In what could be good news for Indian drug makers, the import of active pharmaceutical ingredients (APIs) and other raw materials from China has resumed.

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India readies massive COVID-19 testing plan

In a move that indicates India is readying for massive novel coronavirus (COVID-19) testing, Indian Council of Medical Research (ICMR) has sought price quotes for the supply of 10 lakh antibody kits (serological test) for diagnosis of COVID-19.

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The Veeda Newsletter

ISSUE 03: MAR 2020

Message from our Executive Director, Mr. Ajay Tandon sharing his thoughts on the recent Covid-19 situation and the measures taken by Veeda to control it.

As the world continues to grapple with the still evolving COVID-19 pandemic, we are paying close attention to expert recommendations and regulatory guidance to determine our approach to preventing, detecting, containing and mitigating the impact of a potential outbreak of the infection in our ecosystem. Some of the policy measures and protocols adopted by us are:

- Increasing awareness about COVID-19 : its symptoms, the protective measures to mitigate its incidence and spread, and the actions to be taken in case of suspected infection
- Encouraging precautionary measures amongst employees : allowing flexible and remote working arrangements within teams, reducing large group gatherings, restricting travel, daily screening and tagging of employees at all facilities, and encouraging self-containment when symptomatic
- Encouraging precautionary measures amongst employees : allowing flexible and remote working arrangements within teams, reducing large group gatherings, restricting travel, daily screening and tagging of employees at all facilities, and encouraging self-containment when symptomatic
- Scenario planning for potential incidences during and after clinical studies
- Enhanced housekeeping measures : more frequent disinfection of the clinical as well as non-clinical areas, easy access to hand sanitizers and availability of masks

We will continue to review and enhance our measures in response to emerging challenges and will endeavor to maintain business continuity through this uncertain period, to support our clients while ensuring the safety and wellbeing of our employees and clinical volunteers. We will continue to keep our clients updated on any developments and consequent changes in our ability to maintain planned operations.

We are also evaluating the recent guidelines released by MHRA and USFDA regarding the management of patient trials at remote hospital sites under the current situation and will discuss any changes required to these studies in accordance with these guidelines with our clients.

We urge everyone to be responsible and careful and wish you all good health."

Ajay Tondon,
Executive Director

The Veeda Newsletter

ISSUE 03: MAR 2020

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